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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,143	11/12/2001	Carol W. Readhead	18810-81609	6154

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,143

Applicant(s)

READHEAD ET AL.

Examiner

Joseph T. Woitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 135-145 is/are pending in the application.
- 4a) Of the above claim(s) 138-142 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 135-137, 143 and 145 is/are rejected.
- 7) ☒ Claim(s) 144 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08),
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This application filed November 12, 2001, is a divisional of application 09/191,920, filed November 13, 1998, now US Patent 6,316,692, which claims benefit to provisional application 60/065,825, filed November 14, 1997.

Applicants' amendment filed August 30, 2004, has been received and entered. The specification has been amended. Claims 135, 143 and 145 have been amended.

Claims 135-145 are pending.

Election/Restriction

As indicated in the previous office action Applicant's election of Group I, and the election of the species of a retroviral vectors is acknowledged. The election has been treated as an election without traverse because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement (MPEP § 818.03(a)). Claims 136 and 137 specifically recite the elected transfecting agent of a retroviral vector and claims 135, 143, 144 and 145 are generic to the elected invention. Claims 138-142 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claims 135-137 and 143-145 are currently under examination to the extent they encompass the elected invention drawn to a kit comprising: (1) a retroviral vector as a transfecting agent, (2) a polynucleotide comprising a gene in operable linkage with a promoter, and optionally (3) a polynucleotide encoding a selectable genetic marker.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

The amendment to the specification has addressed the issue regarding the claim for priority.

Claim Objections

Claims 135-137 and 143-145 stand objected to because as noted previously it is upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. However, no generic claim is found allowable and the claims broadly encompass non-elected inventions. The claims should be amended to reflect the elected invention.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 135-137, 143-145 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendments to the claims have addressed each of the specific basis of the rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 135-137 and 145 stand rejected and newly amended claim 143 is under 35 U.S.C. 102(b) as being anticipated by Bosselman *et al.* (US Patent 5,162,215).

Applicants note that the claims have been amended and that the amendments distinguish the claimed invention from that disclosed by Bosselman *et al.* More specifically, Applicants argue that the limitation directing the kit for a specific together with the instructions should entitle the instructions to be treated with patentable weight. See Applicant's amendment, page 7. Applicant's arguments have been fully considered, but not found persuasive.

In the discussion related to the instructions recited in the claims, it was indicated that the Examiner in determining the patentable weight of the instructions relied on the findings of *In re Gulack*, *In Re Woodruff*, *In re Shetty* 195 USPQ 753 and *In Re Marshall*. The critical question posed is whether there exists any new and unobvious functional relationship between the printed matter and the substrate (citing page *In re Gulack*, 404 "B"). In this case there is no functional

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relationship between a viral vector and printed material where the instructions were required for the functionality of the viral vector. The ability of the vectors taught by Bosselman *et al.* are inherent to each of the vectors. Applicants do not contest that the vectors are different only the intended use, as further distinguished by instructions for this use. Citing *In Re Woodruff* 16 USPQ2d 1934 it was argued that new uses for a product known in the prior art does not provide patentability to the old compound. Applicant's retroviral vector containing a polynucleotide encoding a gene product and optionally a marker is not disclosed as having a "completely new" use as it was well known in the art at the time of filing to use retroviral vectors to transfect cells and to provide the expression of heterologous transgenes. Further, it was noted in the basis of the previous rejection that the Bosselman *et al.* reference was not relied upon as a showing of the use of the product for the transfection spermatogonia cells and the recitation "for the transfection of a male non-human vertebrate's germ cells" was not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Structurally the claims requires a composition comprising: (1) a retroviral vector as a transfecting agent, (2) a polynucleotide comprising a gene in operable linkage with a promoter, and optionally (3) a polynucleotide encoding a selectable genetic marker. Bosselman *et al.* teach a recombinant retroviral vector containing a gene of interest. Bosselman *et al.* teach that any

gene of interest can be provided such as hormones (see claim 5) and includes the teaching for use of a selectable marker genes such as neomycin (see claim 4). Bosselman *et al.* teaches that the retroviral vectors can be used to transfect mouse egg cells, male pronuclei (column 1, starting on line 46 and column 3, starting on line 21). Bosselman *et al.* provide a retroviral vector that anticipates the limitations set forth in the claims and provides the same intended use for the vector for transfecting germ cells.

Therefore, for the reasons above and of record, the rejection is maintained.

Conclusion

No claim is allowed. Claim 144 is free of the art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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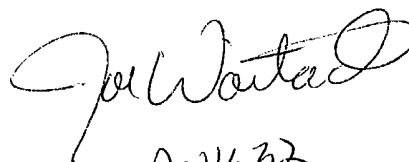
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



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